In the United States Court of Federal Claims

No. 03-620V

(Filed Under Seal: May 15, 2006)[1]
(Reissued: May 18, 2006)

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ADELA QUINTANA DE BAZAN, Petitioner, v. SECRETARY OF THE DEPARTMENT OF HEALTH AND HUMAN SERVICES, Respondent.	Petition for review of special master's decision; National Childhood Vaccine Injury Act, 42 U.S.C. §§ 300aa-1 to 300aa-34; causation; petitioner's *prima facie* case; shift of burden of proof to respondent to establish another cause once petitioner has established a *prima facie* case; 42 U.S.C. § 300aa-13(a); remand

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OPINION AND ORDER

LETTOW, Judge.

Petitioner, Adela Quintana De Bazan, seeks review of a decision by a special master dated February 7, 2006, denying compensation under the National Childhood Vaccine Act of 1986, Pub. L. No. 99-660, § 311, 100 Stat. 3743, 3756 (Nov. 14, 1986) (codified, as amended, at

[1]In accord with the Rules of the Court of Federal Claims, App. B, Rule 18(b), this opinion and order was initially filed under seal. Each party was afforded fourteen days from the date of the sealed filing to object to the public disclosure of any information supplied by that party. The parties promptly advised that no redactions were necessary, and thus the entire decision is being made public.

42 U.S.C. §§ 300aa-1 to -34) ("Vaccine Act"). Ms. De Bazan alleged that her receipt of a tetanus-diphtheria ("Td") vaccination caused her to develop acute disseminated encephalomyelitis ("ADEM"), a disorder characterized by damage to the central nervous system, which resulted in severe health problems and has left petitioner in a quadriplegic state.

The special master denied relief to Ms. De Bazan on the ground that she failed to satisfy her burden of proof that her ADEM developed within a temporally appropriate time. Specifically, he ruled that the vaccine could not have caused the onset of Ms. De Bazan's symptoms because those symptoms appeared too soon, *i.e.*, within twelve hours, after her vaccination. *De Bazan v. United States*, No. 03-620V, slip op. (Fed. Cl. Spec. Mstr. Feb. 7, 2006) ("Entitlement Decision"). For the reasons set out below, the court concludes that the special master misapplied the burdens of proof that appertain to a petitioner and respondent in a vaccine case. In particular, the special master failed first to determine whether petitioner had met her burden of making out a *prima facie* case of causation before proceeding to determine whether respondent had met its burden of proving that Ms. De Bazan's ADEM was the result of some cause other than the Td vaccine. The special master in effect improperly collapsed the analysis and required Ms. De Bazan not only to prove her *prima facie* case by a preponderance of the evidence, but also to disprove respondent's rebuttal case by a preponderance of the evidence. Upon review of the evidence adduced during the proceedings before the special master, the court determines that Ms. De Bazan established a *prima facie* case by a preponderance of the evidence. Accordingly, this case will be remanded to the special master for determination whether respondent can meet its burden of showing by a preponderance of the evidence that petitioner's illness was the result of some cause other than the Td vaccination Ms. De Bazan received.

BACKGROUND AND PROCEDURAL HISTORY[2]

ADEM is a disorder of the central nervous system ("CNS") arising when one's own immune system produces cells that destroy the myelin, the material that sheathes and protects the nerves. Entitlement Decision at 3. The exact cause of ADEM is unknown. *Id*. at 4. The expert witness who testified for the government, Dr. Subramaniam Sriram, opined that in 30 to 50 percent of ADEM cases the triggering event is unexplained. *Id*. at 3. The special master concluded that based on the evidence presented, the adverse immune response is typically triggered by a viral or bacterial infection or by a vaccination, and that it can also occur spontaneously. *Id*. at 3-4.

Ms. De Bazan, an ostensibly healthy, active adult woman approximately 49 years of age, received a Td vaccination at some time before 11:00 a.m. on April 19, 2000. Entitlement Decision at 2. During the medical visit at which the vaccine was administered, Ms. De Bazan's medical records noted that she had a sore throat, swelling on the left of her neck, and nasal

[2]The factual background is largely drawn from the factual findings of the special master. Other findings of fact are based upon the submissions and testimony presented to the special master, and rulings on questions of law and of mixed fact and law are set out in the analysis.

discharge, but the special master found that there was insufficient evidence to show that petitioner was suffering from a viral or bacterial infection at the time. *Id*. at 3. By 9:00 p.m. on the same day the vaccine was administered, Ms. De Bazan began to experience symptoms of soreness in her arms, numbness, and a general decline in health that can be associated with ADEM. *Id*. at 2. By May 2, 2000, petitioner's symptoms had become so severe that she was unable to walk without assistance, and she sought emergency medical attention. *Id*. On May 8, 2000, she was admitted to a hospital, and currently Ms. De Bazan remains hospitalized in a quadriplegic state as a result of her condition. Petitioner's Motion for Review and Memorandum of Objections ("Pet.'s Mot.") at 1.

The diagnosis of ADEM is not disputed. Both petitioner and respondent agree that respondent suffers from ADEM, and that petitioner began exhibiting symptoms of ADEM approximately 11 hours after the vaccination. Entitlement Decision at 2. In a preliminary ruling issued on March 18, 2005, the special master determined that "the only real questions left in this case are (1) can Td cause ADEM and (2) did this particular vaccination cause-in-fact [p]etitioner's ADEM." *Id*. Stated another way, the key question for the special master was "whether Td can cause ADEM with onset 11 hours post-vaccination." *Id*. at 6. To answer this question, the special master held an entitlement hearing for the purpose of taking expert testimony. *Id*. at 2. Petitioner's expert witness was Dr. Susan Hansen, who is also petitioner's treating neurologist. *Id*. Dr. Hansen is Board-certified in neurology, electrodiagnostic medicine, and clinical neurophysiology, and is an adjunct and associate professor at Stanford University's School of Medicine and affiliated with its Medical Center. *Id*. at 2-3. Dr. Hansen has seen approximately five cases of ADEM during her career. *Id*. at 3. The government called Dr. Subramaniam Sriram, who is the director of the multiple sclerosis clinic at Vanderbilt Medical Center. *Id*. In that capacity, Dr. Sriram conducts clinical research concerning treatments for immunological diseases affecting the central nervous system and basic scientific research involving animal models. *Id*. Dr. Sriram is Board-certified in internal medicine and neurology; he sees approximately 5 to 6 cases of ADEM each year. *Id*.

Dr. Hansen provided testimony based primarily on her observations of Ms. De Bazan as one of her treating physicians as well as case reports of ADEM and related illnesses. Entitlement Decision at 7. Based upon these sources, it was Dr. Hansen's opinion that the Td vaccine can cause ADEM, and that the onset of ADEM can occur within hours of vaccination. Dr. Hansen presented two different lines of analysis to show that onset of ADEM can occur so rapidly. First, Dr. Hansen explained that some studies showed the onset of ADEM within hours of a triggering event (*e.g.*, exposure to a vaccine). *Id.* Secondly, Dr. Hansen maintained that studies showed that neurological illnesses similar to ADEM have been observed to appear within hours of the triggering event; by analogy, Dr. Hansen testified that the onset of ADEM could occur within the same interval of time. *Id.* at 8.

The special master rejected both of Dr. Hansen's rationales. First, the special master examined several of the studies cited by Dr. Hansen and found that he disagreed with Dr. Hansen's interpretation that the studies showed that the onset of ADEM could occur within

hours of a triggering event. Entitlement Decision at 7-8. The special master particularly discounted Dr. Hansen's testimony in this respect because it conflicted with Dr. Sriram's testimony. In rejecting Dr. Hansen's testimony and alternate rationales, the special master appeared to adopt a set of circumscribing time limitations suggested by Dr. Sriram as being necessary for development of ADEM. *Id*. at 3-5, 10. Based upon research with animal models, Dr. Sriram testified that it takes a minimum of five to seven days from the time of an immunization or other immunological trigger before the immune system can be stimulated to produce a sufficient number of lymphocytes to traverse the circulatory system into the brain and other elements of the central nervous system. *Id*. at 4. Then, again based upon research with animal models, Dr. Sriram indicated that a further period is required for amplification in the brain before the disease manifests itself. *Id*. Overall, Dr. Sriram concluded that it would take from 10 to 14 days from the time of introduction of an immunological trigger, such as an infection or vaccination, for ADEM to manifest itself. *Id*. at 4-5.

Second, the special master rejected Dr. Hansen's analogy between ADEM and similar neurological disorders. Dr. Hansen testified regarding studies that showed that the Td vaccine had caused demyelinating diseases in the peripheral nervous system ("PNS") that began within hours of vaccination. Entitlement Decision at 8-9; *see* Pet.'s Mot. at 7-8.[3] Although diseases of the central nervous system ("CNS") (including ADEM) and those involving the peripheral nervous system are distinct, "injuries which affect the CNS and those affecting the PNS are presumed to have the same immunopathogenesis." Entitlement Decision at 3 (citing Pet. Ex. 22, *The Merck Manual of Diagnosis and Therapy*, Sec. 14, ch. 180).[4] The special master, however, found that "Dr. Hansen fails to adequately explain why cases involving the PNS . . . can be properly analogized to those involving the CNS." *Id*. at 8-9. To support his rejection of the analogy, the special master relied largely upon Dr. Sriram's testimony that "[j]ust because you have an inciting antigen that causes peripheral nervous system demyelinating disease, that does not necessarily extend the assumption that [the inciting antigen] can also cause central nervous system demyelinating disease." *Id*. at 4. Dr. Sriram's opinion in this regard was based largely on the fact that the myelin in the central nervous system and that in the peripheral nervous system are somewhat different in structure (*e.g.*, they do not contain all of the same proteins or exactly the same membrane structures). *Id*. at 3-4.

Ultimately, the special master credited Dr. Sriram's testimony with respect to the medically appropriate lapse of time necessary for the onset of ADEM and rejected Dr. Hansen's testimony because he found Dr. Sriram to be more reliable. Entitlement Decision at 9-10. The

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[3]The peripheral nervous system concerns the arms and legs and does not include the brain, brain stem, optic nerves, and spinal cord. Entitlement Decision at 3. PNS conditions include brachial neuritis, polyradiculopathy, and Guillane-Barré Syndrome. *Id*.

[4]"Pet. Ex." refers to the exhibits attached to petitioner's original petition before the special master.

special master determined that petitioner's ADEM manifested itself too soon to be caused by the Td vaccination, and denied recovery. *Id*.

Petitioner filed a Motion for Review of the special master's entitlement decision on March 6, 2006, and the government filed its response on April 5, 2006. This court held a hearing in this case on April 25, 2006. Post-hearing submissions were received from the parties on May 1, 2006 and May 9, 2006.[5] The case is ready for disposition.

STANDARD FOR REVIEW

The Vaccine Act authorizes this court to review decisions by special masters in vaccine cases:

> (2) Upon the filing of a motion [to review a special master's decision], the United States Court of Federal Claims shall have jurisdiction to undertake a review of the record of the proceedings and may thereafter –
> . . .
> (B) set aside any findings of fact or conclusion of law of the special master found to be arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law and issue its own findings of fact and conclusions of law.

42 U.S.C. § 300aa-12(e)(2)(B). In short, the Vaccine Act requires this court to analyze conclusions of law made by a special master under the Vaccine Act to determine whether they are "not in accordance with law." *Id*. Factual findings by a special master may be set aside if they are found to be arbitrary or capricious or if a special master has abused his or her discretion in making such findings. *See id*. The Federal Circuit has commented that "[i]f the special master has considered the relevant evidence of record, drawn plausible inferences and articulated a rational basis for the decision, reversible error will be extremely difficult to demonstrate." *Hines v. Secretary of the Dep't of Health & Human Servs.*, 940 F.2d at 1518, 1528 (Fed. Cir. 1991).

ANALYSIS

The legal standards for establishing causation are at issue in this case. Under the Vaccine Act, causation may be established in one of two ways: through a statutorily-prescribed presumption of causation upon a showing that the injury falls under the Vaccine Injury Table

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[5]The government's post-hearing submission on May 1, 2006, raised no new issues but rather provided additional citations to the record respecting matters already in dispute. Petitioner's submission on May 9, 2006, however, put forward new matters that had not been made part of the record before the special master. In its disposition of this case, the court has not considered the new materials provided by petitioner.

("Table injury"), *see* 42 U.S.C. § 300aa-14,[6] or where the injury is not listed in the Vaccine Injury Table ("off-Table injury") by proving causation in fact. *See* 42 U.S.C. §§ 300aa-11(c)(1)(C)(ii)(I), -13(a)(1). Tetanus toxoid vaccines, including Td, are listed in the Vaccine Injury Table. *See* 42 C.F.R. § 100.3(a). However, ADEM is not listed on the Vaccine Injury Table; therefore, Ms. De Bazan sought redress for her illness under the Vaccine Act's compensatory provisions for off-Table injuries. As a result, Ms. De Bazan had the obligation to prove by a preponderance of the evidence that the Td vaccination caused her ADEM. *See Althen v. Secretary of Health & Human Servs.*, 418 F.3d 1274, 1278 (Fed. Cir. 2005) (citing *Shyface v. Secretary of Health & Human Servs*., 165 F.3d 1344, 1352-53 (Fed. Cir. 1999); *Hines*, 940 F.2d at 1525); *see also* 42 U.S.C. § 300aa-13(a)(1).

A. The Statutory Imperative for a Shifting Burden of Proof

The Vaccine Act explicitly allocates the burden of proof regarding causation first to the petitioner and then conditionally to respondent. In pertinent part, 42 U.S.C. § 300aa-13(a) provides:

> (1) Compensation shall be awarded under the [Vaccine Injury] Program to a petitioner if the special master or court finds on the record as a whole–
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> (A) that the petitioner has demonstrated by a preponderance of the evidence the matters required in the petition by section 300aa-11(c)(1) of this title, and
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> (B) that there is not a preponderance of the evidence that the illness, disability, injury, condition, or death described in the petition is due to factors unrelated to the administration of the vaccine described in the petition.
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> The special master or court may not make such a finding based on the claims of a petitioner alone, unsubstantiated by medical records or by medical opinion.
>
> (2) For purposes of paragraph (1), the term "factors unrelated to the administration of the vaccine"--
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> (A) does not include any idiopathic, unexplained, unknown, hypothetical, or undocumentable cause, factor, injury, illness, or condition, and
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> (B) may, as documented by the petitioner's evidence or other

[6]The initial Vaccine Injury Table was published at 42 U.S.C. § 300aa-14(a). The table can be revised by the Secretary of Health and Human Services acting pursuant to notice-and-comment rulemaking under the authority of 42 U.S.C. § 300aa-14(c). The current version of the Vaccine Injury Table, as amended, is set out at 42 C.F.R. § 100.3.

> material in the record, include infection, toxins, trauma . . . , or metabolic disturbances which have no known relation to the vaccine involved, but which in the particular case are shown to have been the agent or agents principally responsible for causing the petitioner's illness, disability, injury, condition, or death.

The burden thus initially is on the petitioner to prove her *prima facie* case by a preponderance of the evidence. Once a petitioner has successfully put forward her *prima facie* case, the burden shifts from the petitioner to the respondent to prove by a preponderance of the evidence that the petitioner's injury was caused by some factor other than the vaccine. *See* 42 U.S.C. § 300aa-13(a)(1); *Shalala v. Whitecotton*, 514 U.S. 268, 270-71 (1995) (Table injury); *Althen*, 418 F.3d at 1278 (off-Table injury); *Knudsen v. Secretary of the Dep't of Health and Human Servs.*, 35 F.3d 543, 547 (Fed. Cir. 1994) (Table injury); *Paulmino v. Secretary of the Dep't of Health and Human Servs.*, 69 Fed. Cl. 1, 11-12 (2005); *Wagner v. Secretary of Health and Human Servs.*, 37 Fed. Cl. 134, 137 (1997); *McClendon v. Secretary of the Dep't of Health and Human Servs.*, 24 Cl. Ct. 329, 333 (1991) (the "[Vaccine] Act implicitly places the onus of proving the existence of an alleged alternative cause squarely on the shoulders of the respondent." (citing *Mathews v. Secretary of the Dep't of Health & Human Servs*., 18 Cl. Ct. 514, 518-19 (1989))), *aff'd*, 41 F.3d 1521 (Fed. Cir. 1994).

In *Althen*, the Federal Circuit defined the burden a petitioner initially must carry to show causation: "[a petitioner's] burden is to show by preponderant evidence that the vaccination brought about her injury by providing: (1) a medical theory causally connecting the vaccination and the injury; (2) a logical sequence of cause and effect showing that the vaccination was the reason for the injury; and (3) a showing of a proximate temporal relationship between vaccination and injury." *Althen*, 418 F.3d at 1278.[7] If a petitioner "satisfies this burden, she is 'entitled to recover unless the [government] shows, also by a preponderance of evidence, that the injury was in fact caused by factors unrelated to the vaccine.'" *Id*. (quoting *Knudsen*, 35 F.3d at 547) (alteration in original).

The Federal Circuit's very recent decision in *Capizzano v. Secretary of Health and Human Servs.*, 440 F.3d 1317 (Fed. Cir. 2006), picks up the logical threads of the test for causation under the Vaccine Act where *Althen* left off. In *Capizzano*, the court of appeals emphasized the role of treating physicians in addressing the second element of the three-part test for causation set out in *Althen*, *i.e.*, a logical sequence of cause and effect between a vaccination and injury. The chief special master in *Capizzano* had rejected diagnoses from a petitioner's four treating physicians that her rheumatoid arthritis was caused by her hepatitis B vaccination, on the ground that the treating physicians had relied primarily on the temporal relationship of the vaccination to the injury rather than epidemiologic or other scientific evidence of causation. 440

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[7]The "proximate temporal relationship" has alternatively been described as a "medically-acceptable temporal relationship between the vaccination and the onset of the alleged injury." *Althen*, 418 F.3d at 1281.

F.3d at 1323. The trial court affirmed. In reversing, the Federal Circuit ruled that the treating physicians' reliance on circumstantial evidence of a logical sequence of cause and effect was probative and would suffice to establish a *prima facie* case even where such evidence did not rise to the level of scientific or medical proof. *Id*. at 1325-26. The court in *Capizzano* recognized that this elaboration of the second element of the *Althen* test touched on the statutory allocation of proof between a petitioner and respondent:

> There may well be a circumstance where it is found that a vaccine *can* cause the injury at issue and where the injury was temporally proximate to the vaccination, but it is illogical to conclude that the injury was actually caused by the vaccine. A claimant could satisfy the first and third prongs without satisfying the second prong when medical records and medical opinions do not suggest that the vaccine caused the injury, or where the probability of coincidence or another cause prevents the claimant from proving that the vaccine caused the injury by preponderant evidence. *See* 42 U.S.C. § 300aa-13(a)(1)(B) ("Compensation shall be awarded . . . if the special master or court finds on the record as a whole . . . that there is not a preponderance of the evidence that the . . . injury . . . is due to factors unrelated to the administration of the vaccine described in the petition.").

Id. at 1327.[8]

In this context, the statutory framework for allocating burdens of proof respecting causation can be critically important, as it is in this case. Instructive in this regard is a pre-*Althen*, pre-*Capizzano* decision that holds as a matter of law that for an off-Table injury, Subparagraph (A) of 42 U.S.C. § 300aa-13(a)(1) requires the petitioner to bear the burden of "eliminat[ing] other possible causes of the condition . . . that exist in the record." *Pafford v. Secretary of the Dep't of Health and Human Servs*., 64 Fed. Cl. 19, 30 (2005), *appeal docketed*,

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[8]In this respect, *Capizzano* quotes the negative, second part of the causation showing prescribed by 42 U.S.C. § 300aa-13(a)(1)(B), *i.e.*, "there is *not a preponderance* of the evidence that the illness . . . is due to factors unrelated to the administration of the vaccine." (emphasis added). That the statute uses the negative form of words to describe the showing that the illness was due to causes other than the vaccine should not be read to require the claimant to prove the negative. *See Knudsen*, 35 F.3d at 549; *Wagner*, 37 Fed. Cl. at 138-39; *cf. Whitecotton*, 514 U.S. at 270-71 (stating in affirmative terms that "the Secretary of Health and Human Services may rebut a *prima facie* case by proving that the injury or death was in fact caused by 'factors unrelated to the administration of the vaccine.'" (quoting 42 U.S.C. § 300aa-13(a)(1)(B)). Indeed, as the Federal Circuit has held, "the standards that apply to a petitioner's proof of actual causation in fact in off-table cases should be the same as those that apply to the government's proof of alternative actual causation in fact." *Knudsen*, 35 F.3d at 549.

No. 05-5106 (Fed. Cir. Apr. 13, 2005). *Pafford* cites *Munn v. Secretary of the Dep't of Health and Human Servs*., 970 F.2d 863 (Fed. Cir. 1992), for the proposition that "an actual-causation vaccine petitioner 'must prove by a preponderance of the evidence that the vaccine, *and not some other agent*, was the actual cause of the injury.'" *Pafford*, 64 Fed. Cl. at 30 (quoting *Munn*, 970 F.2d at 865) (emphasis added in *Pafford*).

This court respectfully disagrees with the conclusion in *Pafford* that *Munn* supports collapsing the statutory allocation of burdens of proof for an off-Table injury such that a petitioner bears an obligation both to establish a *prima facie* case that the vaccination caused her injury and that some other agent was not the cause. First, the statement from *Munn* quoted in *Pafford* appears to be a dictum, because *Munn* involved an allegation of a Table injury and not an off-Table, actual-causation injury. *See Munn*, 970 F.2d at 867. Second, the quoted portion of *Munn* appears to conflict with the Supreme Court's and Federal Circuit's explications in *Whitecotton*, *Althen*, and *Knudsen* of the statutory shift in burden of proof once petitioner puts forward a *prima facie* case for causation. *See supra*, at 7. Moreover, the elaboration of the *Althen* test in *Capizzano* did not recalibrate this shift in burdens of proof. Rather, *Capizzano* explained the type of proof that can be adduced by a petitioner to make out a *prima facie* case, and it recognized how that proof might affect the corresponding burden shifted to the respondent. Here, as will be discussed *infra*, Ms. De Bazan adduced evidence both of literal temporal proximity and of a plausible medical theory that proximately tied her vaccination to the onset of her injury.[9]

The shifting burdens of production and proof provided by the Vaccine Act are particularly important when dealing with an area of medical science that is as poorly understood as ADEM and where there is admitted uncertainty as to causation among medical experts. As recently described by the Federal Circuit in *Althen*, the preponderance standard prescribed by the statute does not demand scientific certainty and allows use of circumstantial evidence by injured parties. *Althen*, 418 F.3d at 1280; *see also Capizzano*, 440 F.3d at 1325-26; *Knudsen*, 35 F.3d at 549.

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[9]Notably, the overarching analytical construct set out in *Pafford* would, if followed, lead to a different result in this case. In *Pafford*, the court commented that

> if the petitioner has succeeded in presenting only evidence of biologic plausibility and a literal temporal proximity, the Special Master may look to other facts apparent in the record, including potential alternative causes, that may undermine the petitioner's case and lead the Special Master to conclude that the petitioner has failed to establish causation-in-fact. That a vaccine *may* cause a specific response or condition is not proof that it did in a particular case.

Pafford, 64 Fed. Cl. at 31 (citing *Hodges v. Secretary of the Dep't of Health and Human Servs.*, 9 F.3d 958, 961-62 & n.4 (Fed. Cir. 1993)). This commentary fails to take account of the statutory allocation of burdens of proof.

The *Althen* court commented that the system created by Congress for compensating vaccine injuries is a system in which "close calls regarding causation are resolved in favor of injured claimants." 418 F.3d at 1280 (citing *Knudsen*, 35 F.3d 549 (explaining that "to require identification and proof of specific biological mechanisms would be inconsistent with the purpose and nature of the vaccine compensation program"). *Althen* involved a factual setting very similar to the case at hand, *i.e.*, "the possible link between TT [tetanus toxoid] vaccination and central nervous system injury, a sequence hitherto unproven in medicine." 418 F.3d at 1280. Under these circumstances, the *Althen* court indicated that a petitioner could build her case based upon circumstantial evidence and stated that the "purpose of the Vaccine Act's preponderance standard is to allow the finding of causation in a field bereft of complete and direct proof of how vaccines affect the human body." *Id*; *see also Bunting v. Secretary of the Dep't of Health and Human Servs.*, 931 F.2d 867, 873 (Fed. Cir. 1991) ("scientific certainty" is not the standard of proof).

B. Petitioner's Proofs of Causation

In accord with the statutory commands of the Vaccine Act, the court must first determine whether petitioner has met her burden of production and proof in establishing a *prima facie* case that petitioner's Td vaccination was the cause-in-fact of her injury. *See Althen*, 418 F.3d at 1278; *Knudsen*, 35 F.3d at 547; *Kelley v. Secretary of Health and Human Servs.*, 68 Fed. Cl. 84, 97-102 (2005). Because the special master in effect assigned all of the burden of proof of causation to petitioner, *see* Entitlement Decision at 6 & n.5 (citing *Pafford*), 9-10, not mentioning that respondent may also have a burden of proof, the court determines that the special master applied legal standards that are not in accord with law.

In his entitlement decision, the special master found at the outset that "[p]etitioner has not demonstrated by preponderant evidence a *prima facie* element of her claim - that the onset of her ADEM occurred within a medically appropriate time frame." Entitlement Decision at 1. Even though the Entitlement Decision purported to find that petitioner had not established an element of petitioner's *prima facie* case, the Entitlement Decision did not, in fact, first determine whether petitioner had successfully made out a *prima facie* case before turning to respondant's rebuttal case. The special master improperly collapsed the two-part inquiry in Subparagraphs (A) and (B) of 42 U.S.C. § 300aa-13(a)(1) and determined that petitioner's illness must have been caused by some factor other than the Td vaccine primarily because the timing of Ms. De Bazan's illness did not fit with the model for onset posited by respondant's expert Dr. Sriram. The special master did not make findings as to an actual alternative cause, but his analysis assumes that there must have been an alternative cause because acceptance of Dr. Sriram's model demands finding an alternative cause. It was legal error for the special master to assume an alternative cause of petitioner's ADEM based upon his acceptance of respondent's model. *See Althen*, 418 F.3d at 1278. The special master should first have determined whether petitioner had successfully put forward a *prima facie* case, then required respondent to prove alternative causation by a preponderance of the evidence. *Id*.

The court thus concludes that the special master misapplied the burdens of proof and production that are required by the Vaccine Act. Because the special master's decision was "not in accordance with law, the court must review the record in this case to draw its own conclusions of fact and law." *Kelley*, 68 Fed. Cl. at 100; *see Althen*, 418 F.3d at 1281 (citing 42 U.S.C. § 300aa-12(e)(2)(B); *Saunders v. Secretary of the Dep't of Health and Human Servs.*, 25 F.3d 1031, 1033 (Fed. Cir. 1994)). Petitioner's evidence will be tested with each of the causation elements identified in *Althen*.

1. Petitioner's proof of a causal medical theory.

Petitioner's expert witness, Dr. Hansen, acknowledged that there is no diagnostic test to distinguish the cause of ADEM; *i.e.*, there is no test that will define with medical certainty the biological trigger of a specific individual's ADEM. Hr'g Tr. 14:4 to 16:12 (May 13, 2005).[10] However, Dr. Hansen explained that there are numerous tests that allow physicians to rule out disorders other than ADEM and other possible causes of a patient's symptoms. In that regard, Dr. Hansen noted that a number of studies were performed on Ms. De Bazan, "none of which identified a bacterial, fungal, [or] viral condition or any evidence of multiple sclerosis." *Id*. at 15:23 to 16:9.

In addition to this process of identifying ADEM and of excluding other possible disorders and causes, Dr. Hansen put forward a mechanism that would explain the onset of Ms. De Bazan's ADEM as well as the timing of the onset. Referring to a number of peer-reviewed articles on the subject, Dr. Hansen testified that a likely cause of ADEM is a process described as "molecular mimicry". Pet. Ex. Tab 71 at 6 (Second Supplemental Report and Declaration of Susan R. Hansen, M.D. (Apr. 21, 2005)). Similar to the animal model described by Dr. Sriram, *see supra*, at 4, the "molecular mimicry" process described by Dr. Hansen posits that the introduction of a trigger such as an infectious agent or vaccine could stimulate the immune system to produce lymphocytes that are designed to destroy the trigger but which divide to produce chemical mediators called cytokines that are harmful to myelin or its components. Entitlement Decision at 4; Pet. Ex. Tab 71 at 6 (citing Pet. Ex. Tab 26 (S. Schwarz, et al., *Acute Disseminated Encephalomyelitis, A Follow-up Study of 40 Adult Patients*, 56 Neurology 1313 (2001)); Pet. Ex. Tab 27 (P.G. Jorens, et al., *Encephalomyelitis-associated Antimyelin Autoreactivity Induced by Streptococcal Exotoxins*, 54 Neurology 1433 (2000)); Pet. Ex. Tab 28 (H. Hartung, et al., *ADEM: Distinct Disease or Part of the MS Spectrum?*, 56 Neurology 1257, 1259 (2001))).

In addition to the molecular-mimicry mechanism posited by Dr. Hansen, petitioner submitted an article suggesting another possible mechanism for ADEM development. The article describes a hypothesis whereby injury to blood vessels (vasculopathy) precedes and initiates demyelination. Pet. Ex. Tab 43 at 292 (Louis Reik, *Disseminated Vasculomyelinopathy: An*

[10]The citations to the Hearing Transcript and to other evidence adduced before the special master are to the entitlement hearing held on May 13, 2005, except where otherwise noted.

Immune Complex Disease, 7 Annals of Neurology 291 (1980)). Under this hypothesis, the introduction of a foreign antigen could result in an immune response that damages blood vessels, which in turn causes injury to the nervous system. *Id*. This process could explain how a single trigger could result in injury to both the central and peripheral nervous systems. *Id*. The existence of this additional hypothesis for ADEM development, while uncorroborated by any additional evidence in the record, demonstrates the uncertainty surrounding the causation of ADEM, and suggests that there may be more than one pathway for development of ADEM and similar illnesses.

In addition to these two models of mechanisms by which ADEM could develop from a Td vaccination, petitioner adduced direct evidence to show that the Td vaccine can cause ADEM and other demyelinating diseases of the central nervous system. First, she posited that some studies showed development of ADEM as a result of Td vaccination. Secondly, petitioner sought to draw an analogy between ADEM and other demyelinating disorders not involving the central nervous system, and she cited examples of rapid onset of these other demyelinating disorders, as described in various scientific journals.

The articles cited from medical journals linking the Td vaccination with ADEM did not provide an evident pattern for development of the illness. One case study cited described a healthy 43-year-old individual who developed ADEM twenty days after receiving a tetanus toxoid vaccination. Pet. Ex. Tab 24 (Okan Bolukbasi and Mehmet Ozmenoglu, *Acute Disseminated Encephalomyelitis Associated with Tetanus Vaccination*, 41 Eur. Neurology 231 (1999)). A second case study discussed a healthy seven-year-old boy who first developed ADEM and then optic neuritis[11] after receiving a diphtheria-tetanus-poliomyelitis (DTP) immunization; the onset of the first symptoms was within two weeks of the vaccination. Pet. Ex. Tab 25 at 136-37 (J. Mancini, et al., *Relapsing Acute Encephalopathy: A Complication of Diphtheria-Tetanus-Poliomyelitis Immunization in a Young Boy*, 155 Eur. J. Pediatrics 136 (1996)). The authors of this case study stated that they could not exclude the possibility that the boy's illness and the vaccination were "coincidental phenomena," but explained that "[t]he repetition of adverse events . . . suggests a cause-and-effect relationship between the DTP vaccination and the involvement of the central nervous system." *Id*. at 138. The authors could not state which of the three antigens (diphtheria, tetanus, or poliomyelitis) was the likely cause of the boy's illness. *Id*. Petitioner also submitted a review of published case studies, performed by the Institute of Medicine ("IOM"). Pet. Ex. Tab 34 (IOM, Vaccine Safety Committee, *Adverse Events Associated with Childhood Vaccines* (Kathleen Stratton, et al., eds., 1994)). This review described six cases in which individuals developed demyelinating disorders of the central nervous system that clinically resembled ADEM after receiving tetanus vaccinations. The onset of symptoms in four of these cases ranged from three to ten days after vaccination (the data were insufficient to determine time of onset in the other two cases). *Id*. at 84-85. Because of the relatively small number of case reports and the lack of specificity in those reports, the review

[11]The authors of this report describe ADEM and optic neuritis as "two different expressions of the same disease." Pet. Ex. Tab 25 at 138.

concluded that "[t]he evidence is inadequate to accept or reject a causal connection between tetanus toxoid, DT, or Td and demyelinating diseases of the CNS (ADEM, transverse myelitis, and optic neuritis)." *Id*. at 85-86.

The second set of articles tended to show a causal connection between the tetanus vaccine and demyelinating disorders involving the peripheral nervous system. One such demyelinating disorder is polyneuropathy. *See* Pet. Ex. Tab 35 at 918 (S. Lane Rutledge and O. Carter Snead III, *Neurologic Complications of Immunizations*, 109 J. of Pediatrics 917 (1986)). The Rutledge and Snead study summarized the results of a number of published case studies and stated that polyneuropathy is the "most common reported neurologic complication of tetanus toxoid." *Id*. Another case study provided evidence not only of a correlation between a tetanus vaccination and polyneuritis, but actual causation. Pet. Ex. Tab 11 (J.D. Pollard and G. Selby, *Relapsing Neuropathy Due to Tetanus Toxoid*, 37 J. of the Neurological Scis. 113 (1978)). In this case study, the authors observed an individual "who inadvertently received three separate injections of tetanus toxoid over a period of 14 years and developed an acute demyelinating polyneuropathy soon after the injection on each occasion." *Id*. at 114. With each injection, the latency period between vaccination and the onset of symptoms grew shorter. On the first occasion, symptoms developed in three weeks; on the second occasion, symptoms developed in two weeks; on the third occasion, symptoms developed in ten days. *Id*. A final case study proffered by petitioner described the case of an individual who developed initial neurological symptoms the evening after he received a Td vaccination. Pet. Ex. Tab 57 at 56 (Patti Holliday and Raymond Bauer, *Polyradiculoneuritis Secondary to Immunization with Tetanus and Diphtheria Toxoids*, 40 Archives of Neurology 56 (1983)). The individual was ultimately diagnosed with polyradiculoneuritis, a disorder of the peripheral nervous system. *Id*. The individual in this case study had previously received two doses of tetanus toxoid with no negative effects. *Id*.

In sum, the case studies from medical journals and Dr. Hansen's alternate postulates for mechanisms provide probative evidence of a causal medical theory by which Td can cause ADEM. Moreover, although the structure and composition of myelin differs to some extent between the central nervous system and the peripheral nervous system, the cases of demyelinating disorders of the peripheral nervous system identified by Dr. Hansen are nevertheless probative of whether the Td vaccine can result in demyelinating disorders generally. The studies showing a correlation between tetanus vaccination and demyelinating disorders of the peripheral nervous system bolster petitioner's argument that Td can cause demyelinating disorders of the central nervous system, including ADEM.

Based upon all of the evidence presented by petitioner, the court concludes that petitioner has shown by a preponderance of the evidence that although the occurrence is rare, Td vaccine can cause ADEM.

2. Petitioner's proof of a logical sequence of cause and effect.

Petitioner proffered evidence indicating that her ADEM was the result of the Td vaccination she received on April 19, 2000. Ms. De Bazan relied primarily upon the opinions of her four treating physicians, each of whom indicated that they believe that she suffers from ADEM and that her ADEM was caused by her Td vaccination. As described *supra*, at 11, Dr. Hansen testified at the entitlement hearing that petitioner is suffering from ADEM and that petitioner's ADEM was caused by her Td vaccination. Hr'g Tr. 9:5 to 12:13. Petitioner also tendered the affidavits of her three other treating physicians, each of whom stated their opinion that petitioner's Td vaccination was the cause of her ADEM. Dr. Jacqueline Adler, who is certified in tropical medicine, has taught at the University of Health Sciences in Phnom Penh, Cambodia, and later acted as the clinician editor within the Center for HIV Information at the University of California, San Francisco School of Medicine. Dr. Adler personally examined and treated Ms. De Bazan. Pet. Ex. Tab 38 at 1-2 (Report of Adler (Jan. 8, 2004)). Dr. Adler has expertise in providing health maintenance to people relocating to the United States from abroad, as well as in making vaccine recommendations to patients going abroad. *Id*. at 2. Dr. Adler reported that Ms. De Bazan's "ADEM was very likely a reaction to her Td vaccination on April 19, 2000." *Id*. at 14. Petitioner also proffered the affidavit of Dr. Sheila Humphries. Pet. Ex. Tab 3 (Declaration of Humphries (Feb. 20, 2003)). Dr. Humphries is an internist at El Camino Hospital in Mountain View, CA. *Id*. at 7. Dr. Humphries took a medical history of Ms. De Bazan, performed a physical examination of Ms. De Bazan on May 8, 2000, and reviewed copies of Ms. De Bazan's medical history. *Id*. at 1-3. Based upon her analysis of this information, Dr. Humpries expressed her opinion that "the temporal sequence of events leading up to Mrs. Bazan's illness strongly supports a cause and effect argument for the vaccination being the cause of the illness." *Id*. at 5. Finally, petitioner proffered the affidavit of Dr. Ronald Hoffman. Pet. Ex. Tab 2 (Declaration of Hoffman (March 11, 2003)). Dr. Hoffman is a neurologist who formerly served as a clinical instructor in neurology at the Stanford University School of Medicine. *Id*. at 6. Dr. Hoffman is affiliated with El Camino Hospital and was a treating physician for Ms. De Bazan "during her acute hospitalization." *Id.* at 2. Based upon his personal observations as well as a review of selected records of Ms. De Bazan's hospitalization, Dr. Hoffman concluded that "all of [Ms. De Bazan's] neurologic deficits . . . were the direct result of the patient's postvaccinal [ADEM]." *Id.* at 4.

Section 300aa-13(a)(1) of the Vaccine Act allows circumstantial evidence and medical opinion as proof of causation. *Capizzano*, 440 F.3d at 1324-26; *Althen*, 418 F.3d at 1280. Accordingly, the court concludes that the circumstantial evidence and the medical opinions of Ms. De Bazan's four treating physicians that the Td vaccination caused Ms. De Bezan's injury are sufficient proof of a logical sequence of cause and effect in her case.

3. Petitioner's showing of a proximate temporal relationship between vaccination and injury.

As described in the Entitlement Decision, petitioner sought to establish that it was medically plausible for the onset of petitioner's ADEM to occur within hours of her Td vaccination, primarily through Dr. Hansen's testimony and published reports and case studies.

Entitlement Decision at 7-9. Petitioner maintains that one of the proffered studies demonstrates development of demyelinating disorders of the central nervous system as a result of the Td vaccination within an eleven-hour time period, and that other reports demonstrate that demyelinating disorders not involving the central nervous system had similarly developed within hours of vaccination. The court does not agree with petitioner's interpretation of the proffered published reports and case studies regarding the time of onset of demyelinating disorders of the central nervous system. The shortest latency periods shown in the proffered materials between a triggering event and onset of a central nervous system demyelinating disorder like ADEM were 2 and 3 days. In one study of incidents of adverse events associated with tetanus vaccine, the study disclosed that a child developed symptoms of a CNS demyelinating disorder three days after receiving a tetanus booster. Pet. Ex. Tab 34 at 84-85. Another study of reported cases of ADEM and MDEM (multiphasic disseminated encephalomyelitis) noted that "[t]he mean latency between predemyelinating illness and the onset of neurological signs was 13.0 days," but with a range of two to 31 days. Pet. Ex. Tab 15 at 2410 (R.C. Dale et al., *Acute Disseminated Encephalomyelitis, Multiphasic Disseminated Encephalomyelitis and Multiple Sclerosis in Children*, 123 Brain 2407 (2000)).

However, proffered case studies involving demyelinating disorders of the peripheral nervous system reveal onset of symptoms within hours of the triggering event. A summary of studies submitted by petitioner shows that some patients developed symptoms of demyelinating disorders of the peripheral nervous system such as polyneuropathy within hours of vaccination. Pet. Ex. Tab 35 at 919. One study reporting data collected by a vaccine manufacturer identified twenty-two different cases involving the peripheral nervous system in the 1970s. *See* Pet. Ex. Tab 62 at 26 (Ute Quast et al., *Mono- and Polyneuritis After Tetanus Vaccination*, 43 Developments in Biological Standardization 25 (1979)). In cases reported by this study, the onset of symptoms began as soon as three hours after vaccination. *Id*. at 28-30.

Again, the myelin of the central and peripheral nervous systems are very similar but differ somewhat in composition and structure. However, as noted previously, because the pathogenesis of peripheral nervous system disorders is believed to be similar to those of the central nervous system, the timing of onset of disorders of the peripheral nervous system is probative of the onset timing of disorders of the central nervous system. *See supra*, at 3-4.

Of particular importance to the timing of the onset of petitioner's symptoms is the issue of prior vaccination. Previous vaccination is important because an individual may be "primed" for an immune response by prior exposure to an infection or other triggering agent (a process described as "sensitization" or "rechallenge"). Several studies proffered by petitioner indicated that repeated vaccinations can tend to increase the likelihood of a neurological injury and to accelerate the response. One published study warned that "there is [a] possible connection of serious neuropathy with repeated injections, [and] a careful history or prior immunization should be taken before administering routine booster injections." Pet. Ex. Tab 35 at 918. Another published study describes an individual who suffered demyelinating disorders after each of three different vaccinations with tetanus toxoid, with onset of symptoms occurring more rapidly with each successive vaccination. *See supra*, at 13.

During the onset hearing held before the special master, Adela Bazan Quintana, petitioner's daughter, testified that she did not know whether Ms. De Bazan had received an earlier tetanus vaccination. Hr'g Tr. 45:12-17 (Apr. 27, 2004). Similarly, Victor Bazan Diaz, petitioner's husband, testified that even though he thought petitioner had received a tetanus vaccination "maybe 15 years" before, he was not sure whether this was so. *Id*. at 76:7-13. Nonetheless, documentary evidence indicates that Ms. De Bazan likely received prior tetanus vaccinations. A medical history taken on April 19, 2000 reported that Ms. De Bazan had received a tetanus booster "10-11 [years] ago". Pet. Ex. Tab 16 at 58 (Medical Records from Alviso Health Center). In addition, Dr. Adler, who specializes in tropical medicine, stated in her report that because neonatal tetanus is a significant problem in South America, "much attention is given to the routine immunization of pregnant women." Pet. Ex. Tab 38 at 14. Based upon Ms. De Bazan's background (Ms. De Bazan had had three children in Peru) and information provided by her husband, Dr. Adler estimated that petitioner's vaccination on April 19, 2000 was likely petitioner's "5th or 6th vaccine." *Id*. Accordingly, Dr. Adler believed that petitioner "was more likely to suffer an adverse reaction to this last Td vaccination than most residents of the United States." *Id*. The court finds that it was more likely than not that petitioner had previously received several tetanus vaccinations.

Particularly given Ms. De Bazan's prior exposure to Td vaccine, the court concludes that her relatively rapid onset of an adverse reaction after she received a Td vaccination on April 19, 2000 established a proximate temporal relationship between the vaccination and her injury.

4. Synopsis.

Overall, the court concludes that petitioner has met her burden of showing by a preponderance of the evidence that her Td vaccination could have caused, and more likely than not did cause, her onset of ADEM symptoms within 11 hours. The government maintained at the hearing held before the court on April 25, 2006 that petitioner had not proven her *prima facie* case because (1) the Td vaccine cannot cause ADEM, *see* Hr'g Tr. 30:15 to 31:11 (Apr. 25, 2006), and (2) based upon the literature and Dr. Sriram's model, it is not possible for onset of ADEM to occur within 11 hours of a triggering event such as a vaccination or infection. *Id*. at 27:10 to 29:17. The evidence indicates that cases associating a Td vaccination with ADEM are relatively rare and that proof of such an association does not rise to the level of scientific certainty, as the IOM report discussed *supra*, at 12-13, states. However, the evidence indicates that this may well be such a rare case, and the resulting proofs of the three *Althen* elements satisfy the preponderance standard that applies in this instance. *See Bunting*, 931 F.2d at 873. Secondly, the government's impossibility postulate based on the rapid onset of Ms. De Bazan's symptoms following her vaccination rests largely on Dr. Sriram's animal model of a mechanism by which ADEM *can* be caused. This model, admittedly, does not explain all causes of ADEM, nor does it adequately take into account the increasingly rapid adverse responses that may occur when a sensitized individual is repeatedly exposed to a triggering cause. Finally, the impossibility postulate does not take account of the fact that disorders of the peripheral nervous

system have occurred within hours after a vaccination.[12] In short, the government's challenges to petitioner's *prima facie* case are rejected.

Having satisfied the three-part test set out in *Althen*, the court determines that Ms. De Bazan has established a *prima facie* case that her Td vaccination on April 19, 2000 was the cause-in-fact of her injuries. *Althen*, 418 F.3d at 1281-82; *Kelley*, 68 Fed. Cl. at 100-102; *Rodriguez v. Secretary of Health and Human Services*, 67 Fed. Cl. 409, 410-11 (2005); *cf. Whitecotton*, 514 U.S. at 273-76.

C. Respondent's Case

The government maintains that even if petitioner has proven her *prima facie* case, her injury was caused by some triggering event other than her Td vaccination, such as an infection.

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[12]The special master additionally indicated that Dr. Hansen's analogy between PNS and CNS demyelination had to be discounted because the special master determined that petitioner had failed to show any anecdotal examples where ADEM was caused rapidly by a Td vaccination. The special master stated that if "PNS and CNS are substantially similar, one would expect to see anecdotal cases indicating the manifestation of a CNS injury within hours of vaccination as with the case reports involving PNS." Entitlement Decision at 9. The special master found it "quite probative" that petitioner had failed to produce "even one single, directly analogous case or anecdote." *Id.* This argument, however, is a *non sequitur*. The special master in effect states that because he finds no evidence that CNS disorders have not been observed to manifest themselves within hours of vaccination, the analogy between CNS and PNS disorders must be inapposite. However, given the extreme rarity of ADEM, and particularly vaccine-induced ADEM, as well as the fact that the triggering cause of ADEM was not determined in as many as half of the cases, it is not apparent why the special master found the lack of anecdotal examples of ADEM onset within hours to be a substantial factor in invalidating the possible similarities between CNS disorders and PNS disorders.

The special master additionally indicated that Dr. Hansen's analysis was unreliable because it lacked scientific rigor, citing the special master's "gatekeeping function" required by *Daubert v. Merrell Dow Pharms., Inc*, 509 U.S. 579, 597 (1993). Entitlement Decision at 9-10. The special master commented that Dr. Hansen's testimony was weakened by the fact that Ms. De Bazan's case was not reported in medical journals, implying that Dr. Hansen's diagnosis of rapid-onset ADEM was invalid without peer review. *Id*. at 9 n.6. A special master assuredly should apply the factors enumerated in *Daubert* in addressing the reliability of an expert witness's testimony regarding causation. *See Terran v. Secretary of Health and Human Servs.*, 195 F.3d 1302, 1316 (Fed. Cir. 1999). However, neither *Terran* nor the Vaccine Act provide a basis for a special master to draw an adverse inference from the fact that a treating physician failed to report her diagnosis of petitioner's illness in a peer-reviewed scientific journal.

That question is unresolved. Under the Vaccine Act, respondent may rebut petitioner's prima facie case if it can show by preponderant evidence that petitioner's illness was caused by "factors unrelated to the administration of the vaccine." 42 U.S.C. § 300aa-13(a)(1)(B); *see Althen*, 418 F.3d at 1278. In the entitlement decision, the special master stated that based upon a review of petitioner's medical records, "the [c]ourt cannot say there is preponderant evidence of a viral or bacterial infection in the medical records." Entitlement Decision at 2. However, in making that observation, the special master was not endeavoring to make a determination whether respondent had shown by preponderant evidence that petitioner's illness was not caused by "factors unrelated to the administration of the vaccine," as described by 42 U.S.C. § 300aa-13(a)(1)(B) and (a)(2).

The government maintained at the hearing held before the court on April 25, 2006 regarding petitioner's Motion for Review that "clearly [respondent] believe[s] that there was evidence of a preexisting condition," acknowledging that the special master "did not find preponderant evidence that this was so." Hr'g Tr. 36:18-21. Because of the special master's misallocation of the shifting burdens of proof, he appears not to have conducted a full inquiry into other potential causes of petitioner's injury. The government should be allowed to put forward a full rebuttal case and should be provided with an opportunity to prove by a preponderance that petitioner's illness was caused by some factor other than the vaccination, in accord with 42 U.S.C. § 300aa-13(a)(1)(B). Because the court is remanding this case to the special master for disposition, *see infra*, the special master should receive additional evidence from respondent and petitioner on the issue of alternative causation.

CONCLUSION

For the foregoing reasons, petitioner's motion for review is GRANTED, the decision of the special master dated February 7, 2006, denying compensation is REVERSED, and the case is REMANDED to the special master for proceedings to determine whether respondent can show by a preponderance of evidence that petitioner's illness was the result of some cause other than Ms. De Bazan's Td vaccination. Thereafter, the special master should proceed to determine whether compensation is due to petitioner, and if compensation is due, how much compensation is appropriate.

It is so ORDERED.

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Charles F. Lettow
Judge